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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STEELE, AMBER D

ART UNIT

PAPER NUMBER

1639

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,412	Applicant(s) KIM ET AL.	
	Examiner AMBER D. STEELE	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2009 and 26 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 12-34 is/are pending in the application.
- 4a) Of the above claim(s) 12-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 31-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-30 were originally filed on September 18, 2006.

The preliminary amendment received on September 18, 2006 amended claims 1, 6, 8, 11, 12, and 15.

The amendment received on December 22, 2009 amended claims 1-7, canceled claims 8-11, and added new claims 31-34.

Claims 1-7 and 12-34 are currently pending.

Claims 1-7 and 31-34 are currently under consideration.

Election/Restrictions

2. Applicants elected, without traverse, Group I (previous claims 1-11) in the reply filed on May 29, 2009. Claims 12-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

3. Upon further consideration, the species requirement is withdrawn.

Priority

4. The present application claims status as a 371 (National Stage) application of PCT/US05/08973 filed March 18, 2005 which claims the benefit of U.S. Provisional application 60/554,538 filed March 19, 2004.

Withdrawn Objections

5. The various objections to claims 1-12 are withdrawn in view of the claim amendments received on December 22, 2009.

Withdrawn Rejections

6. The various rejections of claims 1-11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of the claim amendments received on December 22, 2009.

New Objections

Claim Objections

7. Claim 5 is objected to because of the following informalities: hydrogel (polyarylamide-based) coating should read “polyacrylamide-based hydrogel coating” (see typographical error regarding polyacrylamide and clarification of claim limitations – i.e. polyacrylamide is required by the claim). Appropriate correction is required.

8. Claims 2-5 and 7 are objected to because of the following informalities: the claim language is excessive and redundant. Independent claim 1 sets out the method steps of the method, dependent claims 2-5 and 7 are utilized to further limit the reagents utilized in the deposition step. Therefore, claim language reiterating the method step of deposition recited in independent claim 1 in each of dependent claims 2-5 and 7 is excessive and redundant. For example, dependent claim 2 could be written as “[t]he antibody microarray screening method according to claim 1 wherein the antibodies are specific for proteins selected from the group

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consisting of drug-metabolizing enzymes and proteins functionally related with said drug-metabolizing enzymes”. Appropriate correction is required.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-7 and 31-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **new matter** rejection. Support for the claim amendments received on December 22, 2009 was not found in the originally filed disclosure. For example, support for the method steps of “hybridizing the plurality of spots of antibodies with a plurality of labeled target proteins”, “quantifying the label signal strength produced at each spot”, “quantifying the levels of target protein captured at each spot on the basis of label signal strength”, “comparing levels of target protein among the plurality of samples of labeled target proteins”, and the method steps of claims 6, 31, 32, 33, and 34 was not found in the originally filed specification. In addition, support for the following ranges was not found in the originally filed specification: at least one enzyme (see present claim 4), 10-1000 fold dilution, and 5-500 µg/ml (see present claim 34). See MPEP § 2163.05 III regarding ranges. See *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific

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example within the subgenus range) and *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-7 and 31-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. For example, independent claim 1 reads “depositing a plurality of spots of antibodies selected from the group consisting of purified immunoglobulins and fluids that are unprocessed for immunoglobulin isolation”. How can spots of antibodies be purified immunoglobulins (i.e. superfamily which comprises antibodies and other molecules of similar structure) or fluids (i.e. some fluids do not comprise antibodies)? Applicants may wish to clarify the method step by indicating that the samples spotted comprise purified antibodies or fluids comprising antibodies (for example only, please refer to the originally filed specification for support for any claim amendments).

13. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. For example, it is unclear how an enzyme can be selected from the group

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consisting of “mitochondrial proteins, apoptosis-related proteins, anti-oxidant proteins, oxidative stress proteins, and intracellular protein degradation proteins” (e.g. not all mitochondrial proteins are enzymes, etc.).

14. Claims 6 and 31-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. For example, present independent claim 1 requires spotting either antibodies or fluids. However, claims 6 and 31-34 require spotting both antibodies and fluids. Therefore, it is not clear what is required to be spotted on the microarray.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 1 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Haab, Methods and applications of antibody microarrays in cancer research, Proteomics, 3: 2116-2122, 2003 (November).

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For present claims 1 and 5, Haab teaches (a) depositing a plurality of spots of antibodies on predetermined positions of a hydrogel, (b) incubating labeled antigens/epitopes with the antibodies on the hydrogel, (c) quantifying the label at each spot in order to quantify the antigen/epitope, and (d) comparing labels at various spots (please refer to the entire reference particularly pages 2117-2118).

Therefore, the teachings of Haab anticipate the presently claimed method.

17. Claims 1 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Nielsen et al., Profiling receptor tyrosine kinase activation by using Ab microarrays, PNAS, 100(16): 9330-9335, August 5, 2003.

For present claims 1 and 6, Nielsen et al. teach (a) depositing a plurality of spots of antibodies on predetermined positions of a microarray, (b) incubating labeled antigens/epitopes with the antibodies, (c) quantifying the label at each spot in order to quantify the antigen/epitope, and (d) comparing labels at various spots wherein optimization is performed (please refer to the entire reference particularly the abstract; pages 9331-9332; Figure 1).

Therefore, the teachings of Nielsen et al. anticipates the presently claimed method.

18. Claims 1, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al., Antibody microarray profiling of human prostate cancer sera: Antibody screening and identification of potential biomarkers, Proteomics, 3: 56-63, 2003 (January; provided by applicants in the IDS).

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For present claims 1, 5, and 6, Miller et al. teach (a) depositing a plurality of spots of antibodies on predetermined positions of a hydrogel, (b) incubating labeled antigens/epitopes with the antibodies on the hydrogel, (c) quantifying the label at each spot in order to quantify the antigen/epitope, and (d) comparing labels at various spots wherein optimization is performed (please refer to the entire reference particularly the abstract; pages 57-58; Figure 1).

Therefore, the teachings of Miller et al. anticipates the presently claimed method.

19. Claims 1-2, 4, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Haab et al., Protein microarrays for highly parallel detection and quantitation of specific protein and antibodies in complex solutions, *Genome Biology*, 2(2): 1-13, 2001 (provided by applicants in the IDS).

For present claims 1-2, 4, and 6, Haab et al. teach (a) depositing a plurality of spots of antibodies on predetermined positions of a microarray, (b) incubating labeled antigens/epitopes with the antibodies, (c) quantifying the label at each spot in order to quantify the antigen/epitope, and (d) comparing labels at various spots wherein optimization is performed including dilutions (please refer to the entire reference particularly the abstract; pages 2 and 5; Figure 1).

Therefore, the teachings of Haab et al. anticipate the presently claimed method.

20. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Weiner et al. U.S. Patent 7,232,672 filed August 5, 2002 (effective filing date of August 3, 2001).

For present claims 1-7, Weiner et al. teach methods comprising (a) spotting antibodies including antibodies from hybridomas that bind P450 onto hydrogel microarrays, (b) incubating

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labeled antigens/epitopes with the antibodies, (c) quantifying the labels, proteins, etc., and (d) comparing different samples (please refer to the entire specification particularly the abstract, columns 15, 26, 30, 126-128, 131-134, 136, 174-178).

Therefore, the teachings of Weiner et al. anticipated the presently claimed method.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **AMBER D. STEELE** whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1639